

**510(k) Summary
Veran Medical Technologies
Traditional 510(k)
ig4™ EndoBronchial**

Date Prepared:

6/25/09

DEC - 2 2009

510(k) Applicant:

Veran Medical Technologies, Inc.
5743 West Park Avenue
St. Louis, MO 63110
Telephone: (314) 659-8500
Fax: (314) 659-8560
Contact: Scott Wrightstone

Device Information:

Trade Name: ig4™ EndoBronchial
Common Name: CT stereotactic accessory
Classification Name: Computed Tomography X-ray System
Classification Code: JAK

Equivalent Legally-Marketed Devices:

ig4™ Image Guided System (K060903)
superDimension inReach System (K081379)

Device Description:

The ig4™ EndoBronchial is an accessory for a CT System that utilizes electromagnetic tracking technology to locate and navigate endoscopic tools, catheters and guidewires relative to a CT-based model of the tracheobronchial tree. Due to system use to locate structures in soft tissue, the system incorporates a method of gating the location information on soft tissue to the patient's respiration. The ig4™ System consists of an EM tracking accessory, a patient referencing system, an EM field generator and tracking system, software, a computer system, and a pulmonary planning workstation. The EM tracking accessory consists of a navigation guidewire and may include additional navigated endoscopic tools.

Intended Use:

The ig4™ Image Guided System is a stereotactic accessory for Computed Tomography (CT) and endoscopic bronchoscope Systems. The ig4 System is indicated for displaying:

- An interventional instrument such as a biopsy needle, an aspiration needle, or ablation needle on a computer monitor that also displays a CT-based model of the target organ(s).
- A CT-based model of the lungs and images of the tracheobronchial tree to aid a physician in guiding endoscopic tools, catheters or guidewires in the pulmonary tract.

The ig4™ System compensates for the patient's respiratory phases.

The ig4™ System is intended for use in clinical interventions and for anatomical structures where computed tomography and/or endoscopic bronchoscopy are currently used for visualizing such procedures.

Substantial Equivalence:

The primary difference between the ig4™ EndoBronchial and the ig4™ Image Guided System is that the bronchoscopic application is indicated for endobronchial navigation of endoscopic tools, catheters and guidewires rather than percutaneous navigation of interventional instruments.

The main differences between the ig4™ EndoBronchial and the inReach System is that the ig4™ EndoBronchial automatically registers the patient location to the CT-based model via the use of reference points, and compensates for the effects of respiration on soft tissue locations by gating the navigation displays to the point in the respiratory cycle where the CT-scans were acquired.

Dissimilarities between the ig4™ EndoBronchial and the predicate devices do not affect the safety or effectiveness of this device.

Performance Data:

Bench testing on a static phantom and animal testing were completed to demonstrate navigation accuracy. Additionally, biological testing was completed on the EM navigation accessory to demonstrate that there are no biocompatibility issues. As required by Veran Medical Technologies design control processes and risk analysis, all verification and validation activities have been completed by designated individuals and have demonstrated the safety and effectiveness of the device.

Clinical Data:

Clinical tests were not required to demonstrate the safety and effectiveness of the device.

Conclusion:

The information provided in this 510(k) notification supports that the ig4™ EndoBronchial was shown to be substantially equivalent to the inReach System (K081379) for its intended use of navigating endoscopic tools, catheters and guidewires in the pulmonary tract and to the ig4™ Image Guided System (K060903) in automatic 3D registration to a CT-based model of the lungs and navigation of instruments.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC - 2 2009

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Scott Wrightstone
QA/RA Manager
Veran Medical Technologies, Inc.
5743 West Park Avenue
ST LOUIS MO 63110

Re: K091934
Trade/Device Name: ig4™ EndoBronchial
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK, KTI, and LLZ
Dated: November 14, 2009
Received: November 17, 2009

Dear Mr. Wrightstone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

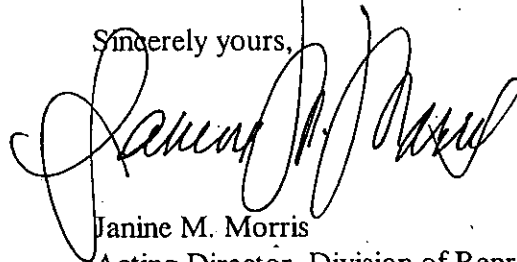
Page 2 -

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4 – Indications for Use

510(k) Number: K091934

Device Name: ig4™ EndoBronchial

Indications for Use:

The ig4™ Image Guided System is a stereotactic accessory for Computed Tomography (CT) and endoscopic bronchoscope systems. The ig4 System is indicated for displaying:

- An interventional instrument such as a biopsy needle, an aspiration needle, or ablation needle on a computer monitor that also displays a CT-based model of the target organ(s).
- Images of the tracheobronchial tree to aid a physician in guiding endoscopic tools, catheters or guidewires, in the pulmonary tract.

The ig4™ System compensates for the patient's respiratory phases.


The ig4™ System is intended for use in clinical interventions and for anatomical structures where computed tomography and/or endoscopic bronchoscopy are currently used for visualizing such procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(Part 21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091934

Page ___ of ___